Henry, Tala

To:

Segal, Mark; Mcclung, Gwendolyn

Cc:

Barone, Stan

ATT00001.htm

Subject:

FW: Statement of Work

Date:

Attachments:

Thursday, April 02, 2015 7:45:28 PM

Mark/Gwen,

See Jeff's request below.

This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

(b)(5)

Tala R. Henry, Ph.D.

Director, Risk Assessment Division

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency

T: 202-564-2959

E: henry.tala@epa.gov

From: Morris, Jeff

Sent: Wednesday, April 01, 2015 1:50 PM

To: Henry, Tala

Subject: FW: Statement of Work

Tala,

I would appreciate RAD's opinion on whether the statement of task in the attached proposal could be strengthened to provide for a useful NAS report. Thanks.

Jeff

From: Jones, Jim

Sent: Wednesday, April 01, 2015 12:09 PM

To: Housenger, Jack; Monell, Marty; Jordan, William; Cleland-Hamnett, Wendy; Morris, Jeff;

Cunningham-HQ, Barbara; Dix, David Subject: Fwd: Statement of Work

Let's discuss. I am inclined to support but want to get your views. Jim

Sent from my iPhone

Begin forwarded message:

From: "Stebbins, Michael J." < Michael J. Stebbins@ostp.eop.gov>

Date: April 1, 2015 at 11:15:05 AM EDT To: "Jones, Jim" < Jones. Jim@epa.gov>

Subject: Statement of Work

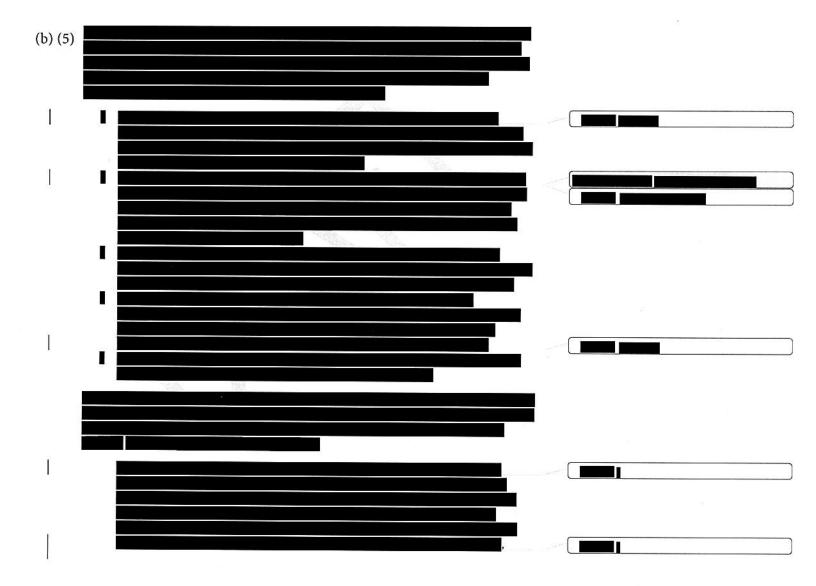


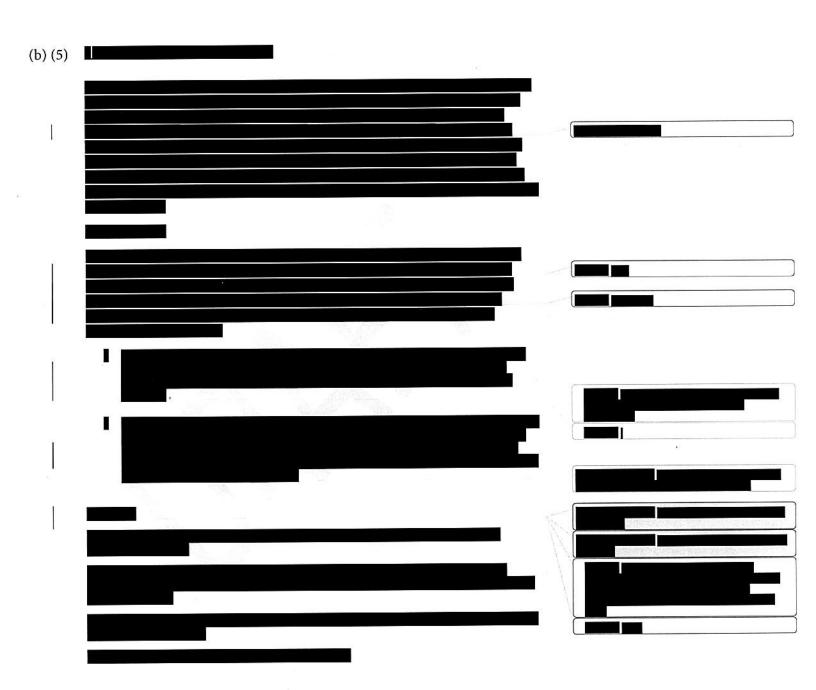
Michael Stebbins, Ph.D. Assistant Director for Biotechnology The White House Office of Science and Technology Policy 202-456-6108

DRAFT, DELIBERATIVE, DO NOT DISTRIBUTE

Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System

Draft: Background and Statement of Task





Segal, Mark

To:

Henry, Tala; Mcclung, Gwendolyn

Cc:

Barone, Stan; Camacho, Iris

Subject:

RE: Statement of Work

Date:

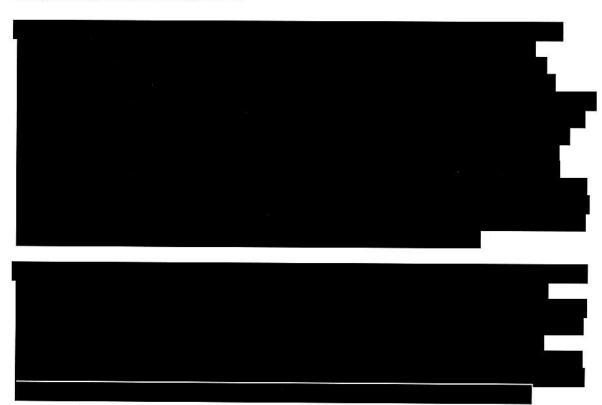
(b)(5)

Monday, April 06, 2015 8:07:37 AM

Attachments:

(b)(5)

I have an edit and some comments.



Mark Segal, Ph.D. segal.mark@epa.gov 202-564-7644

From: Henry, Tala

Sent: Thursday, April 02, 2015 7:45 PM To: Segal, Mark; Mcclung, Gwendolyn

Cc: Barone, Stan

Subject: FW: Statement of Work

Mark/Gwen,

See Jeff's request below.

This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

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Director, Risk Assessment Division Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency

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Date: April 1, 2015 at 11:15:05 AM EDT To: "Jones, Jim" < Jones. Jim@epa.gov>

Subject: Statement of Work

referred to OSTP

Dear Jim,	**
Mike	

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy
202-456-6108

a .		

From: To:

Mcclung, Gwendolyn Henry, Tala; Segal, Mark

Cc:

Barone, Stan; Fehrenbacher, Cathy

Bcc:

Mcclung, Gwendolyn RE: Statement of Work

Subject: Date:

Monday, April 06, 2015 10:41:51 AM

Tala - Here's my thoughts on the NAS Statement of Work that you may pass onto Jeff. My comments follow each (b) (5) of the three bullets



Gwen

Gwendolyn McClung, Ph.D.
Assessment Branch 3
Risk Assessment Division (7403M)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

phone: 202-564-8911 fax: 202-564-9063

email: mcclung.gwendolyn@epa.gov

From: Henry, Tala

Sent: Thursday, April 2, 2015 7:45 PM To: Segal, Mark; Mcclung, Gwendolyn

Cc: Barone, Stan

Subject: FW: Statement of Work

Mark/Gwen,

See Jeff's request below.

This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959 E: henry.tala@epa.gov

From: Morris, Jeff

Sent: Wednesday, April 01, 2015 1:50 PM

To: Henry, Tala

Subject: FW: Statement of Work

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Barbara; Dix, David

Subject: Fwd: Statement of Work

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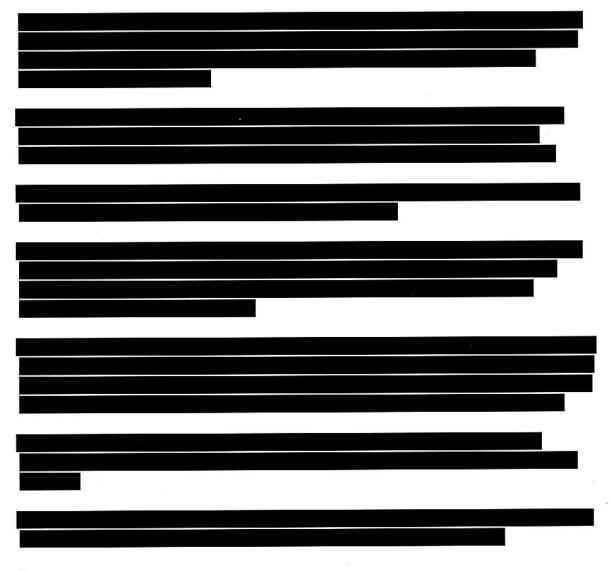
Dear Jim,

referred to OSTP

Mike

Michael Stebbins, Ph.D. Assistant Director for Biotechnology The White House Office of Science and Technology Policy

Attachments:		
leff,		
As a follow-u	up to your request on comments on the NAS SOW., I am forwarding comm	ents from
Mark and Gv	wen that we would like to discuss at Thursday biotech meeting.	
		i i
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3.		
-		
Stanley Baror	ne Jr., M.S., Ph.D.	
	ctor Risk Assessment Division	
	ution Prevention and Toxics	
JS Environm	ental Protection Agency	
202.564.1169	9 office	
202.564.7450		
	9 bb	
202.253.5079		
102.253.5079		



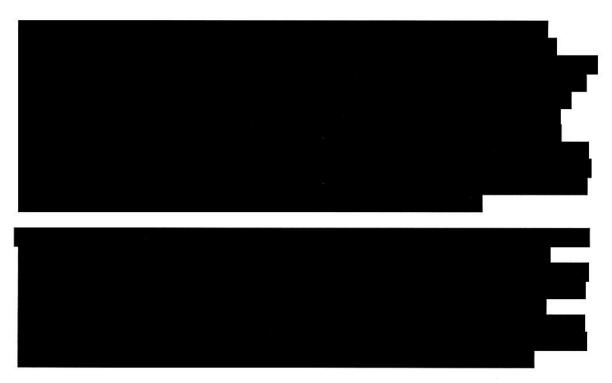
Gwen

From: Segal, Mark

Sent: Monday, April 06, 2015 8:08 AM
To: Henry, Tala; Mcclung, Gwendolyn
Cc: Barone, Stan; Camacho, Iris
Subject: RE: Statement of Work

I have an edit and some comments.

(b)(5)



Mark Segal, Ph.D. segal.mark@epa.gov 202-564-7644

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Sent: Thursday, April 02, 2015 7:45 PM **To:** Segal, Mark; Mcclung, Gwendolyn

Cc: Barone, Stan

Subject: FW: Statement of Work

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This would be a 'task order' to the NAS. Please provide ideas/edits that would make this useful to us.

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

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Subject: Statement of Work

referred to OSTP

Dear Jim,		
	32	*
¥.		
		1
Mike		

Michael Stebbins, Ph.D.
Assistant Director for Biotechnology
The White House
Office of Science and Technology Policy
202-456-6108

Morris, Jeff

To:

Segal, Mark; Mcclung, Gwendolyn

Cc:

Henry, Tala

Subject:

FW: Draft NAS Task Statement

Date:

Monday, April 27, 2015 4:10:26 PM

Attachments:

(b)(5)

Mark and Gwen,

The attached contains combined OPP-OPPT comments on the proposed NAS task statement. I think it incorporates your input. (I had to print the doc to see the redline/strike-outs, which don't show up on my computer screen.)

Jeff

From: Morris, Jeff

Sent: Monday, April 27, 2015 7:32 AM

To: 'Nalubola, Ritu'; Jordan, William; Firko, Michael J - APHIS; McKalip, Doug - OSEC

Subject: Draft NAS Task Statement

Ritu,

Thanks for sharing FDA's comments.

All,

Attached are EPA's comments on the task statement for the proposed study, "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System." I understood from Robbie that he's hoping to get a consolidated set of comments from us. If FDA and USDA are ok with that, then please feel free to add to the attached and send back to me. If you would like a call to discuss comments, I'm happy to have one set up. Thanks.

Jeff

Jeffery T. Morris, PhD
Deputy Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M) Washington, DC 20460

(202) 564-6756

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]

Sent: Friday, April 24, 2015 2:43 PM

To: Jordan, William; Morris, Jeff; Firko, Michael J - APHIS; McKalip, Doug - OSEC

Cc: Linden, Carol; Cournoyer, Patrick **Subject:** RE: Review draft memorandum

referred to FDA

Ritu Nalubola, Ph.D.

Senior Policy Advisor Office of Policy, Office of the Commissioner U.S. Food and Drug Administration WO32, Room 4236

Phone: 301-796-3252 Fax: 301-847-3541

Email: Ritu.Nalubola@fda.hhs.gov

From: Jordan, William [mailto:Jordan.William@epa.gov]

Sent: Monday, April 20, 2015 12:19 PM

To: Firko, Michael J - APHIS; Barbero, Robbie; Nalubola, Ritu; Costanza, Jed; Bucknall, Janet L - APHIS;

Morris, Jeff

Cc: Stebbins, Michael J.; McKalip, Doug - OSEC **Subject:** RE: Review draft memorandum

Robbie –

Both EPA's pesticide group and toxic substances group are interested in the NAS project. Jeff Morris, the Deputy Director for the Office of Pollution Prevention and Toxics can present his group's views, and he will be contacting you directly about what time works for him.

Unfortunately, I have Advisory Committee meeting at both of the times you propose. Would it be possible for me to come late in the afternoon on Friday, i.e., after 5 PM? If not, I will ask Jeff Morris to convey my ideas.

Thanks,

Bill

William Jordan
Deputy Director, Programs
Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049 Fax: 703-308-4776

Mailing Address:

Courier Address:

USEPA Headquarters

Potomac Yards South

Clinton Building

2777 Crystal Drive

1200 Pennsylvania Ave., NW

Room 12-235

Mail Code (7501P)

Arlington, VA

Washington, DC 20460

From: Firko, Michael J - APHIS [mailto:Michael.J.Firko@aphis.usda.gov]

Sent: Monday, April 20, 2015 11:58 AM

To: Barbero, Robbie; 'Ritu.Nalubola@fda.hhs.gov'; 'Jed.Costanza@fda.hhs.gov'; Bucknall, Janet L -

APHIS; Jordan, William; Morris, Jeff

Cc: Stebbins, Michael J.; McKalip, Doug - OSEC

Subject: RE: Review draft memorandum

Robbie,

referred to USDA

Mike

Michael J. Firko, Ph.D., Deputy Administrator

Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

United States Department of Agriculture (USDA)

4700 River Road, Unit 98

Riverdale, MD 20737

Riverdale: (301) 851-3941

DC: (202) 799-7103 mobile: (202) 230-8686

Segal, Mark

To:

Morris, Jeff

Cc:

Mcclung, Gwendolyn; Penalva-Arana, Carolina

Subject: Date: Fw: Request for Information from NAS Committee on Future Biotech Products Friday, June 24, 2016 9:03:03 AM

Attachments:

image001.png

RFI-NAS-Committee-EPA-OPPT.docx

Jeff,

Am forwarding to Gwen and Carolina to make sure we have complete coverage.

From: Laney, Kara N. <KLaney@nas.edu> Sent: Thursday, June 23, 2016 4:37 PM

To: Morris, Jeff

Cc: Segal, Mark; Edelstein, Rebecca

Subject: Request for Information from NAS Committee on Future Biotech Products

Dear Dr. Morris,

I am study director with the National Academies of Sciences, Engineering, and Medicine. I am currently directing the study on future biotechnology products and opportunities to enhance capabilities of the biotechnology regulatory system. The committee is wrapping up the information-gathering phase of the study, and as a part of that, it has put together an RFP to learn about the research investment being made by the federal government in biotechnology.

As you know, in response to a request from the White House Office of Science and Technology Policy, the Academies have convened a committee of experts to identify the kinds of products that may be produced with biotechnology in the next 10 years. The U.S. regulatory system for biotechnology products was originally designed in the 1980s, so the committee will also provide advice on the scientific capabilities, tools, and expertise that may be necessary to regulate those forthcoming products and on whether potential future products could pose different types of risks relative to existing products and organisms. The committee's report is expected to be released at the end of 2016.

The RFP is attached, and it includes a list of suggested search terms as guidelines for the research topics the committee is interested in. The committee would appreciate information about research projects being conducted by the Office of Pollution Prevention and Toxics. A separate request is being sent to the Office of Pesticide Programs. To be of use to its report writing process, the committee set a due date of July 25.

Thanks in advance for your help with this request and please let me know if I can answer any questions.

Best regards,

Kara

Kara Laney

Study Director

Board on Agriculture and Natural Resources

The National Academies of

SCIENCES · ENGINEERING · MEDICINE

500 Fifth Street NW

Washington, DC 20001

Phone: 202-334-1954

Fax: 202-334-1978